

REMARKS

This Response is submitted in reply to the Office Action mailed on January 16, 2008. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-780 on the account statement.

Claims 1, 3, 4, 6-10 and 13-20 are pending. Claims 2, 5 and 11-12 were previously cancelled. In the Office Action, Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103(a). For the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn.

In the Office Action, Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over JP00-2158742 to Yonekubo, et al. ("*Yonekubo*") in view of WO 95/17102 to Georgi, et al. (citing to U.S. Patent No. 5,916,621 ("*Georgi*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 1, 10, 13 and 20 recite, in part, an infant formula comprising hydrolysed sweet whey protein from which caseino-glyco-macropetide has been removed, and a milk protein comprising 5% or more of tryptophan. In contrast, Applicants respectfully submit that the cited references are not combinable and, even if combinable, fail to disclose or suggest every element of the present claims.

The cited references are not combinable because the references teach away from the combination. The Patent Office asserts that, while *Yonekubo* does not teach hydrolysed sweet whey protein with removed casino-glyco-macropetide (CGM), *Georgi* remedies this deficiency by teaching a sweet whey protein produced by the precipitation and removal of caseins, whereby CGM is removed by suitable processes. See, Office Action, page 5, line 9 to page 6, line 6. The Patent Office further asserts that *Georgi* recognizes the need for whey protein with reduced threonine content. See, Office Action, page 5, lines 19-20.

However, by asserting this proposed combination of cited references, the Patent Office ignores the fact that the examples in *Yonekubo* disclose compositions already containing freely added threonine. See, *Yonekubo* (English Translation), page 2, lines 1-5; page 3, lines 1-5; and page 4, Practical Example 1. Therefore, regardless of *Georgi*'s alleged disclosures regarding the need and use of sweet whey protein with reduced CGM and reduced threonine content,

Yonekubo teaches away from the use and need of such manipulated proteins by teaching the addition of threonine to its compositions. Further, the addition of threonine would negate the effects of reduced threonine whey protein anyway, making *Georgi's* alleged teachings ineffective and relatively useless in the compositions of *Yonekubo*.

The Patent Office asserts, however, that even though *Yonekubo* discloses examples where threonine is added to the composition, disclosed examples and preferred embodiments do not constitute teaching away from a broader disclosure or nonpreferred embodiments. In making this assertion, the Patent Office cites *In re Gurley*. See, Office Action, page 7, line 15 to page 8, line 12. In that case, the court concluded that even though the prior art taught epoxy impregnated circuit boards as inferior to polyester-imide resin impregnated circuit boards, Applicant's teaching away argument was insufficient because Applicant asserted no discovery beyond what was known in the art, specifically epoxy impregnated circuit boards. Applicants respectfully submit that the above case and associated argument, cited from MPEP §2145 X(D)(1), is distinguishable from the present combination of cited art.

In contrast to *Gurley*, where the prior art disclosed the claimed invention as inferior, *Yonekubo* does not disclose or even suggest, as inferior, a composition comprising hydrolysed sweet whey protein with removed CGM as required by the present claims. In fact, *Yonekubo* does not even disclose or suggest a composition comprising hydrolysed sweet whey protein with removed CGM at all. Instead, *Yonekubo* teaches compositions with freely added threonine, which results in compositions which directly contrast to the present claims. Therefore, Applicants submit that the Patent Office's assertion based on MPEP §2145 X(D)(1) does not apply with regard to the present invention.

Instead, Applicants submit that MPEP §2145 X(D)(2) applies in that references cannot be combined where the references teach away from the combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). As admitted in the Office Action, *Georgi* teaches that removal of CGM from sweet whey will provide a formula with significantly reduced threonine levels. See, Office Action, page 6, lines 13-16. However, *Yonekubo* teaches compositions already containing freely added threonine. As a result, to combine the cited references would result in a composition still having freely added threonine. This composition would directly contradict the teachings of *Georgi* in that even after removal of CGM from sweet whey, the

formula still would have high threonine levels. Therefore, *Yonekubo* cannot be combined with *Georgi* to arrive at a formula that teaches away the teachings of *Georgi*.

Moreover, Applicants submit that there is no reason to combine the cited references to arrive at the present invention. As stated above, *Yonekubo* teaches compositions with freely added threonine. By contrast to *Yonekubo*, *Georgi* teaches formulas that advantageously have reduced threonine by removing CGM from sweet whey protein. *Georgi* teaches that reduced threonine is necessary to avoid hyperthreoninemia in infants. This teaching directly contradicts the composition disclosed in *Yonekubo*, which already has threonine as an added component. Consequently, one would have no reason to combine references of contradictory teachings to arrive at the present claims.

Even if the cited references are not combinable, Applicants respectfully submit the cited art fails to disclose or suggest every element of the present claims. *Yonekubo* fails to disclose or suggest a composition comprising a milk protein comprising 5% or more of tryptophan as required, in part, by independent Claims 1, 10, 13 and 20. *Georgi* fails to remedy this deficiency, for the Patent Office only relies on *Georgi* to assert the use of hydrolyzed sweet whey protein where CGM has been removed. Consequently, the cited references fail to teach a composition comprising a milk protein comprising 5% or more of tryptophan.

The Patent Office asserts, however, that *Yonekubo* teaches that casein, a tryptophan-rich milk protein, is at 24-32% by weight and has a level of 5% or more of tryptophan. See, Office Action, page 4, lines 4-5. Applicants respectfully disagree. *Yonekubo* never teaches a milk protein having 5% or more of tryptophan. Instead, *Yonekubo* teaches adding L-tryptophan as a separate or free ingredient in the composition. Each time *Yonekubo* discloses tryptophan, it appears as a separate ingredient addition to the composition, not as a sub-component of another ingredient. See, *Yonekubo* (English translation), page 2, lines 1-5; page 3, lines 1-5; and page 4, Practical Example 1.

Further, *Yonekubo* discloses tryptophan as having a separate weight value. This clearly indicates that tryptophan is a separately added ingredient. Moreover, if the Patent Office's assertion is indeed correct, tryptophan would be a sub-component of sodium caseinate. However, in Practical Example 1 of *Yonekubo*, whey powder is listed between sodium caseinate and the amino acid list (including tryptophan), which makes the assertion even more unlikely.

Further, even assuming sodium caseinate includes tryptophan, sodium caseinate is not a tryptophan-rich milk protein. In fact, one skilled in the art would know that sodium caseinate generally has a much lower amount of tryptophan than that required in the present claims. Specifically, sodium caseinate generally contains about 1.1% tryptophan. See, for example, www.americancasein.com/docs/Sodium%20Caseinate.doc; <http://www.casein.com/products.htm>; <http://sci-toys.com/ingredients/casein.html>. Consequently, *Yonekubo* fails to disclose or suggest a milk protein comprising 5% or more of tryptophan as required by the present claims.

The Patent Office further takes the position that because *Yonekubo* teaches whey protein in terms of milk protein serum protein, *Yonekubo* inherently teaches a whey protein with high tryptophan content. Applicants point out, however, that *Yonekubo* specifically teaches, “[t]he amino acids are generally used in free form, but it is possible to use histidine in hydrochloride form.” See, *Yonekubo*, page 3, lines 24-25. Therefore, regardless of what the Patent Office asserts *Yonekubo* inherently teaches, *Yonekubo* plainly states that amino acids, such as tryptophan, are added in free form, with the only stated outlier being histidine, not tryptophan.

For the reasons discussed above, the references are not combinable and, even if combinable, *Yonekubo* and *Georgi* fail to disclose or even suggest all of the elements of the present claims, and thus, fail to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1, 3-4, 6-10 and 13-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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